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OLSON & HIERL, LTD.
36th Floor
20 North Wacker Drive
Chicago, IL 60606

EXAMINER

FALK, ANNE MARIE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/735,138

Applicant(s)

SUTCLIFFE ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8,9,14,30,31,34 and 60-62 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 31 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8,14,30,34,60 and 61 is/are allowed.
- 6) ☒ Claim(s) 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 06 August 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed February 7, 2003 (Paper No. 14) has been entered. Claim 60 has been amended. Claims 10-13, 15, 32, 33, and 35 have been cancelled.

Accordingly, Claims 8, 9, 14, 30, 31, 34, and 60-62 remain pending.

Claims 9 and 31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in Paper No. 12.

Accordingly, Claims 8, 14, 30, 34, and 60-62 are examined herein.

Drawings

New corrected drawings are required in this application because the proposed drawing correction filed on August 6, 2002 has been approved. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to this Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See the specification at page 74, line 25.

It is noted that Applicants have amended the specification to delete the "[http://](http://www.informatics.jax.org)" portion of the hyperlink. However, the remaining text (i.e., www.informatics.jax.org) remains an active hyperlink.

Appropriate correction is required.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 62 stands rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claim is directed to an isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 8. SEQ ID NO: 8 is a fragment of the polypeptide of SEQ ID NO: 1. However, the claimed fragment is not supported by either a specific and substantial asserted utility or a well-established utility because the specification fails to disclose a utility for fragments other than the amidated hcr2 peptide (SEQ ID NO: 9) and neither the specification as-filed nor any art of record disclose or suggest an activity for these polypeptide fragments such that any utility would be well-established for the claimed polypeptide fragment.

Applicants argue that SEQ ID NO: 8 (hcr1) is structurally related to SEQ ID NO: 9 (hcr2) and that both polypeptides are related to the hormone secretin. Applicants further argue that members of the secretin family of gastrointestinal hormones have well established utility. However, the secretin family of hormones have very different functions from that of the hcr2 peptide which is present in the hypothalamus and which has been shown to suppress food intake when injected intracerebroventricularly. Thus, although there is a structural relationship within the secretin family of hormones, the structural similarities pointed to do not correlate with a common function. Applicants argue that the structural similarity of hcr1 to hcr2 and secretin provides sufficient basis to assert that one of skill in the art would have recognized the utility of a new secretin-related polypeptide such as hcr1. Applicant further argues that the hcr polypeptides are hypocretin receptor ligands and have the ability to inhibit hypocretin receptor binding, and thereby inhibit hypocretin function. Applicants point to the specification at page 16, lines 13-21. The specification states that

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“certain hypocretin polypeptides derived from receptor binding portions of hypocretin have the capacity to inhibit the binding of the hypocretin that would normally bind a hypocretin receptor. Thus, the invention also includes hypocretin polypeptides which are specifically designed for their capacity to mimic exposed regions of hypocretin involved in hypocretin receptor binding interactions and thereby receptor function. Therefore, these polypeptides have the capacity to function as analogs to hypocretin, and thereby block function.”

However, the specification does not assert that hcr1 is a “receptor binding portion of hypocretin” and that it therefore would inhibit hypocretin function. Furthermore, the specification does not disclose the activity of hcr1.

Applicants further argue that hcr polypeptides can be used to generate antibodies. However, this does not constitute a **specific** utility, as all polypeptides can be used to generate antibodies.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 62 stands rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The disclosure only presents one skilled in the art with an invitation to experiment.

Conclusion

Claims 8, 14, 30, 34, 60, and 61 are allowable. In Example 7 the specification discloses that SEQ ID NO: 9 (the peptide designated hcr2) suppressed food intake by 40% over the 2 hours following intracerebroventricular administration of 5 µg of the amidated hcr2 peptide.

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This application contains claims 9 and 31 drawn to an invention nonelected without traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 10:30 AM to 8:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, William Phillips, whose telephone number is (703) 305-3482.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, Ph.D.
PRIMARY EXAMINER